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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,213	10/31/2003	Martin T. Gerber	P-11667.00US	1507
27581	7590	10/03/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924				JUNG, WILLIAM C
			ART UNIT	PAPER NUMBER
			3768	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NIT

Office Action Summary	Application No.	Applicant(s)	
	10/698,213	GERBER ET AL.	
	Examiner	Art Unit	
	William Jung	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>31102003</u> | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by *Desai* (US 6,461,296 B1).

Desai anticipates all claimed features in claims 1-23.

Claims 1-3, 5-7, 11, and 20-22: Desai discloses a method and apparatus for delivering a therapeutic agent and surgical tool to the diseased or injured site by imaging the target location such as prostate gland with ultrasound imaging device as shown in figure 3. The surgical tool or device can either be introduced noninvasively via body cavity or invasively via insertion needle where the needle insertion is through the perineum where the treatment fluid, i.e. therapeutic agent such as denervating agent is introduced to the patient. The ultrasound imaging probe 36 provides feedback to verify the location of the needle placed in the patient to deliver the therapeutic agent to desired location. Although a mechanism to cause the distal end of the needle to spring bias into the prostate invasively in figure 3, the noninvasive insertion of the needle to the desired location includes actuating mechanism to control the distal end of the needle, thus, providing equivalent function at the spring bias to cause actuation.

Claims 9, 10, 12-18, and 23: Desai disclosure described above include needle where the needle provides a lumen in which the therapeutic agent is injected with the syringe chamber is a

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reservoir containing the therapeutic agent. In addition, the secondary reservoir is anticipated since figure 2 shows that the syringe 34 is interchangeable to provide multiple therapeutic agent injection from multiple syringes.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4, 8, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Desai* as applied to claim 1, 5-7, and 11 above, and further in view of *Henley et al* (US 6,477,410 B1).

Desai substantially disclose of all claimed features in claims 4, 8, and 19 as described above. However, Desai is silent as to the therapeutic materials being applied to the prostate gland is botulinum toxin. This particular application of botulinum toxin to the prostate gland is well known in the art as evident by Henley et al where the botulinum toxin is applied to prostate gland for therapy. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Henley et al's botulinum toxin injection to prostate gland to the method and apparatus of Desai's image feedback guidance to accurately deliver the botulinum toxin to the prostate gland.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

WL
September 25, 2006

Brian L. Casler
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